AMENDMENTS TO THE SPECIFICATION

Please replace the paragraph [6], with the following rewritten paragraph.

[0001] This application is a Divisional of U.S. patent application no. 10/139,920 filed May 7, 2002, which ~~Under the provisions of 35 U.S.C. § 119(e), this application~~ claims the benefit under the provisions of 35 U.S.C. § 119(e) of U.S. ~~P~~provisional a~~A~~pplication ~~Serial N~~no. 60/289,540, filed on May 7, 2001.

Please replace the paragraph [6], with the following rewritten paragraph.

[0006] Many known differential pressure flow sensors suffer deficiencies when exposed to less than ideal gas and flow inlet conditions and, further, possess inherent design problems with respect to their ability to sense differential pressure in a meaningful, accurate, repeatable manner over a substantially dynamic flow range. This is particularly true when the flow sensor is needed to reliably and accurately measure low flow rates, such as the respiratory flow rates of infants. Proximal flow measured at the patient's airway can be substantially different from flow measured inside or at the ventilator. Many ventilators measure flow, not at the proximal airway, but close to the ventilator. Measurements of flow in this way may result in a substantial difference between the flow, pressure, and volume of gases that are delivered to or exhaled by the patient and that are reported by a pressure or flow sensor which is associated with the ventilator. At least a portion of this discrepancy is because of wasted compression volume, which distends and may elongate a length of respiratory conduit positioned between the patient's airway and the pressure or flow sensor, and humidification or dehumidification attributable to the length of the respiratory conduit between the patient's airway and the pressure or flow sensor. As the compliance of the respiratory conduit may be a known value, some ventilator manufacturers apply a correction for the wasted compression volume. Even when a correction is applied,

precise estimation of the wasted and inhaled portions of the compression volume is difficult because of variations between individual respiratory conduits, the use of humidifiers, the use of heat-moisture exchangers, and other circuit components. Within a typical respiratory conduit, gas conditions (e.g., temperature, pressure, humidity, etc.) may vary considerably, depending upon the distance of the gases from the airway of the monitored individual. As gas conditions nearest the individual are most likely to reflect the corresponding conditions within the individual's airway, the preferred location for monitoring inspiratory and expiratory flows from a patient in the critical care environment is proximal (i.e., as close to the individual's airway as possible).

Please replace the paragraph [7], with the following rewritten paragraph.

[0007] Routine clinical use of differential ~~flowmeters~~ flow meters has increased significantly in the last few years with the development of more robust designs, such as that disclosed in U.S. Patent 5,379,650, issued to Kofoed et al. on January 10, 1995 (hereinafter "the '650 Patent"), the disclosure of which is hereby incorporated herein in its entirety by this reference. The differential flow meter described in the '650 Patent, which has overcome the majority of the problems that were previously encountered when prior differential pressure flow sensors were used, includes a tubular housing containing a diametrically oriented~~diametrically-oriented~~, longitudinally extending strut. The strut of the flow sensor disclosed in the '650 Patent includes first and second lumens with longitudinally-spaced pressure ports that open into respective axially located ~~axially-located~~ notches formed at each end of the strut.

Please replace the paragraph [16], with the following rewritten paragraph.

[0016] The pneumotach may optionally include additional functionality, such as for monitoring the amounts of one or more gases or vaporized substances in the respiration of an individual. By way of example only, the pneumotach may include one or more windows and be configured to have an optical transducer of an infrared sensor or a luminescence-quenching type sensor coupled thereto.

Please replace the paragraph [28], with the following rewritten paragraph.

[0028] FIG. 7 is a perspective assembly view of an exemplary embodiment of a multi-function airway adapter, including a pressure sensing component ~~and~~, an infrared sensing component, and a complementary infrared sensing type transducer that incorporate teachings of the present invention; and

Please replace the paragraph [29], with the following rewritten paragraph.

[0029] FIG. 8 is a perspective assembly view of another exemplary embodiment of a multi-function airway adapter according to the present invention, which includes a pressure sensing component ~~and~~, a luminescence-quenching type sensing component, and a complementarily configured transducer of a luminescence-quenching type sensor.

Please replace the paragraph [31], with the following rewritten paragraph.

[0031] Referring now to FIG. 2, the various features of pneumotach 20 may be configured as known in the art, for example, like the corresponding features of the differential flow sensors that are described in the '650 Patent. Among other things, pneumotach 20 includes a primary conduit 22 and two pressure ports 24 and 34 that are in flow communication with primary conduit 22 through apertures 23 and 33. Also, pneumotach 20 includes an obstruction 21 to block a portion of the flow of respiration or other gases or gas mixtures along the path of primary conduit ~~20~~ 22 and positioned at least partially between pressure port 24 and pressure port 34 to create a pressure differential in the gas flow therebetween. Pneumotach 20 may be formed from an inexpensive, readily mass-producible material, such as an injection moldable plastic, so that pneumotach 20 may be marketed as a disposable unit.

Please replace the paragraph [32], with the following rewritten paragraph.

[0032] Pneumotach 20 is different from the pneumotachs described in the '650 Patent in that, rather than being configured to be coupled to elongate, flexible conduits, or pressure transmission tubes~~,~~ that transport respiratory samples to a remotely located pressure transducer for evaluation, pressure ports 24 and 34 are configured to be coupled directly to corresponding sample ~~conduits~~ ports 54 and 64 ~~(FIGs. 4 and 5)~~, respectively, of a complementarily configured pressure transducer 50 (See ~~FIGs~~FIGS. 4 and 5).

Please replace the paragraph [33], with the following rewritten paragraph.

[0033] As an example, each pressure port 24, 34 may have a sealing element 30, 40 covering an opening 25, 35 of that pressure port 24, 34. As an example and not to limit the scope

of the present invention, each sealing element 30, 40 may comprise a film formed from a material, such as latex, silicone, or the like, that may be pierced by a member (*e.g.*, a needle) and maintain a seal at a pressure of up to about 150 cm H_2O around the piercing member. Also, the material of each sealing element 30, 40 may be formulated to reseal following the removal of a piercing member therefrom.

Please replace the paragraph [34], with the following rewritten paragraph.

[0034] Sealing elements 30 and 40 may also hold filters 29 and 39 within respective pressure ports 24 and 34 of pneumotach 20. Filters 29 and 39 may be positioned within their respective pressure ports 24 and 34 in such a way as to avoid disruption (*e.g.*, piercing, tearing, etc.) thereof when a complementarily configured pressure or flow transducer (*e.g.*, portable pressure transducer 50 shown in FIGs. 4 and 5) having the aforementioned piercing members is coupled to pneumotach 20. Filters 29 and 39 may prevent contamination (*e.g.*, by particulates, moisture, microorganisms, etc.) of a pressure or flow transducer upon coupling of the same to pneumotach 20. By preventing contamination of the pressure or flow transducer, filters 29 and 39 facilitate reuse of the pressure or flow transducer without requiring substantial cleaning or sterilization thereof between uses. Accordingly, a pressure or flow transducer that is complementary to pneumotach 20 may be used with multiple patients. Filters 29 and 39 may comprise any suitable filter medium that will facilitate accurate transmission of a pressure waveform from pressure ports 24 and 34 into a complementary pressure transducer. Suitable media for filters 29 and 39 include, without limitation, hydrophobic, antimicrobial filter materials, such as those typically employed in respiratory conduits, which may be in the form of felt, particles, or otherwise, as known in the art. While it is desirable that filters 29 and 39 not substantially restrict the flow of sampled respiratory gases through pressure ports 24 and 34, some resistance to airflow is allowable, so long as a sufficient differential pressure signal may be

communicated from pressure ports 24 and 34 of pneumotach 20 to a complementarily configured pressure or flow transducer.

Please replace the paragraph [36], with the following rewritten paragraph.

[0036] Alternatively, as depicted in FIG. 3, mechanical retention means, such as the illustrated rings 32 and 42, may be used to secure sealing elements 30 and 40 to their corresponding pressure ports 24 and 34. Each ring 32, 42 is configured to be positioned peripherally (or, as illustrated, circumferentially) around its corresponding pressure port 24, 34. When positioned around a corresponding portion of a pressure port 24, 34, little or no clearance exists between each ring 32, 42 and an adjacent outer surface 26, 36 of the corresponding pressure port 24, 34. Once sealing elements 30 and 40 are appropriately positioned over their respective openings 25 and 35 of pressure ports 24 and 34, respectively, a ring 32, 42 (which may be formed from heat-shrinkable material) or other mechanical retention means may be positioned around its corresponding pressure port 24, 34 and a peripheral portion 31, 41 of the corresponding sealing ~~member~~ element 30, 40 thereon. In this fashion, rings 32 and 42 hold peripheral portions 31 and 41 of the respective sealing members 30 and 40 in place. As depicted, an outer surface 26, 36 of each pressure port 24, 34 may include a peripheral groove 28, 38 formed therein, which is configured to receive at least a portion of a corresponding ring 32, 42, as well as a peripheral portion 31, 41 of a sealing element ~~member~~ 30, 40 positioned between the ring 32, 42 and outer surface 26, 36 of pressure port 24, 34.

Please replace the paragraph [37], with the following rewritten paragraph.

[0037] Turning now to FIGs. 4 and 5, a portable pressure transducer 50 that incorporates teachings of the present invention is illustrated. Portable pressure transducer 50 is configured to

be at least temporarily coupled to a complementarily configured airway adapter that senses respiratory pressure or flow, such as pneumotach 20.

Please replace the paragraph [38], with the following rewritten paragraph.

[0038] Portable pressure transducer 50 includes sample ~~conduits~~ ports 54 and 64, which are positioned in laterally adjacent, spaced apart relation to one another. The distance at which sample ports 54 and 64 are spaced apart from one another, as well as their relative orientations, may facilitate communication with corresponding pressure ports 24 and 34 of pneumotach 20 when portable pressure transducer 50 and pneumotach 20 are assembled with one another. As depicted, sample ports 54 and 64 are each formed at respective coupling ends 56 and 66 of sample conduits 55 and 65 of portable pressure transducer 50. Coupling ends 56 and 66 of sample conduits 55 and 65 protrude from an outer surface 51 of a housing 52 of portable pressure transducer 50, while internal portions 58 and 68 of sample conduits 55 and 65, respectively, are located within housing 52.

Please replace the paragraph [40], with the following rewritten paragraph.

[0040] Housing 52 of portable pressure transducer 50 may include protective sleeves 57 and 67 that may extend therefrom and circumferentially surround coupling ends 56 and 66, respectively, of sample conduits 55 and 65 along substantially their entire external lengths. Protective sleeves 57 and 67 may also extend beyond their respective ~~sample~~ coupling ends 56 and 66 of sample conduits 55 and 65, respectively, so as to prevent coupling ends 56 and 66 from contacting and, when needles are used, from scratching or puncturing other structures, the individual being monitored, or health-care personnel working with or near portable pressure

transducer 50. Protective sleeves 57 and 67 are also configured to receive at least a portion of pressure ports 24 and 34 that correspond to sample ports 54 and 64, respectively.

Please replace the paragraph [42], with the following rewritten paragraph.

[0042] Differential pressure sensor 80 may communicate signals that are representative of the measured difference in pressure between air or gases within sample conduit 55 and air or gases within sample conduit 65 to a processor 102 of a pressure or flow monitor 100, as known in the art (*e.g.,* along a computer communication cable, by wireless transmission, such as infrared transmission, etc.). Processor 102, under control of one or more programs in the form of software or firmware, may then, based on the signals received thereby, employ known principles and algorithms to calculate respiratory flow. Signal conditioning electronics 81 of a type known in the art, such as an instrumentation amplifier, may be associated with differential pressure sensor 80, as known in the art, to amplify the signals that are generated and transmitted thereby as well as reduce or eliminate noise and other signal artifacts. Processor 102 may also quantify airway pressure at different points or portions of the monitored individual's respiration, also by known processes.

Please replace the paragraph [43], with the following rewritten paragraph.

[0043] Sample conduit 55 also communicates with a gauge or ambient pressure sensor 90, which is also in flow communication with the atmosphere external to portable pressure transducer 50. Gauge pressure sensor 90 may be positioned proximally, in reference to the location of the monitored individual, relative to differential pressure sensor 80. In the illustrated example, gauge pressure sensor 90 communicates with the atmosphere by way of a conduit 92 that extends through housing 52 of portable pressure transducer 50 and that opens to the

atmosphere. As gauge pressure sensor 90 communicates with both the atmosphere (*e.g.*, by way of conduit 92) and the airway A (FIG. 1) of an individual I (by way of sample conduit 55, as well as other conduits and ports), gauge pressure sensor 90, which may also comprise a differential pressure sensor, may sense differences between atmospheric pressure and airway pressure. Gauge pressure sensor 90 may be of a type insensitive to one or more of tilt, vibration, movement, or any combination thereof. It may also be desirable for gauge pressure sensor 90 to be insensitive to, or capable of, compensating for common mode pressure variations within the respiratory conduit. As an example and not by way of limitation, gauge pressure sensor 90 may be capable of sensing pressure differences of up to about 120 mm Hg. By way of example only, an XCX Series, dual chip differential pressure sensor available from AllSensors may be used as gauge pressure sensor 90.

Please replace the paragraph [45], with the following rewritten paragraph.

[0045] Portable pressure transducer 50 may also include a valve 60, 70 positioned along each sample conduit 55, 65, between coupling end 56, 66 thereof and differential pressure sensor 80 and/or gauge pressure sensor 90 (*i.e.*, upstream from sensors 80 and/or 90). Each valve 60, 70 controls (*i.e.*, permits or restricts) the flow of respiratory gases through its corresponding sample conduit 55, 65. For example, when valves 60 and 70 are both in open positions, respiratory gases may flow therethrough and, thus, along their respective sample conduits 55 and 65. Conversely, when valves 60 and 70 are closed, respiratory gases are restricted from flowing completely through sample conduits 55 and 65. Exemplary valves that may be used in portable pressure transducer 50 include the three-way solenoid valves marketed under the trade name X-VALVE® by the Pneutronics Division of Parker Hannifin Corporation, which is located in Hollis, New Hampshire, or titanium nickel valves manufactured by TiNi Alloy Company of San Leandro, California. Valves 60 and 70 may be configured to communicate with a control device, such as processor 102 of monitor 100 or a processor of a separate computer (not shown)

associated with monitor 100, which is programmed to actuate valves 60 and 70 and, thus, to control the flow of respiratory gases through sample conduits 55 and 65. Such communication may be effected wirelessly (*e.g.*, by infrared signals or other known, suitable wavelengths of electromagnetic radiation) or via wires or cables.

Please replace the paragraph [48], with the following rewritten paragraph.

[0048] Portable pressure transducer 50 may also include a power provision element 75, such as an interconnection (*e.g.*, a wire or cable) to a remote power source or an internal power source (*e.g.*, a battery) for supplying power to valves 60 and 70, differential pressure sensor 80, gauge pressure sensor 90, and ~~another~~ other power-consuming elements of portable pressure ~~sensor~~ transducer 50.

Please replace the paragraph [49], with the following rewritten paragraph.

[0049] Housing 52 of portable pressure transducer 50 may be configured to prevent moisture-sensitive components thereof, such as differential pressure sensor 80 and gauge pressure sensor 90, from being exposed to moisture (*e.g.*, from humidity, sources of fluid, etc.). In addition, filters 29 and 39 of pneumotach 20 may prevent moisture from coming into contact with these moisture-sensitive components of portable pressure transducer 50. A similar, optional filter 94 may likewise be positioned along conduit 92 to prevent exposure of gauge pressure sensor 90 to moisture from the environment external to housing 52.

Please replace the paragraph [50], with the following rewritten paragraph.

[0050] As an alternative to the embodiments of pneumotach 20 and portable pressure transducer 50 shown in and described with reference to FIGs. 2-5, various features of the pressure ports of the pneumotach and of the coupling ends of the sample conduits of the portable pressure transducer may be reversed, as depicted in FIG. 5A. As shown, a pneumotach 20′ may include pressure ports 24′ and 34′ with hollow needles 27′ and 37′ protruding therefrom. Needles 27′ and 37′ are configured to be coupled with coupling ends 56′ and 66′, respectively, of corresponding sample conduits 55′ and 65′ of a complementarily configured portable pressure transducer 50′. In particular, as the outer diameter of each needle 27′, 37′ is significantly smaller than the inner diameter of a coupling end 56′, 66′ of its corresponding sample conduit 55′, 65′ over which a ~~sealing element~~protective sleeve 57′, 67′, or sealing element, is positioned, each needle 27′, 37′ is configured to roughly align with and temporarily puncture a sealing element 57′, 67′ on a coupling end 56′, 66′ of its corresponding sample conduit 55′, 65′. Needles 27′ and 37′ may comprise any hollow, injection-type needle with a small circumference (*e.g.*, an 18, 20, or 25 gauge needle) and a tip which will readily pierce sealing element 57′, 67′. Sealing elements 57′ and 67′ may be formed from any material that will form an adequate seal (*e.g.*, a seal which may be maintained at pressures of up to about 150 mm Hg) around the outer surface of a needle 27′, 37′, while substantially resealing upon removal of a needle 27′, 37′ therefrom. Exemplary materials that may be used as sealing elements 57′ and 67′ include, without limitation, films of latex, silicon, and other relatively soft, resilient elastomeric materials.

Please replace the paragraph [51], with the following rewritten paragraph.

[0051] In another exemplary embodiment of both a pneumotach and portable pressure transducer that incorporate teachings of the present invention, corresponding elements of these

apparatus are configured to matingly engage one another upon assembly of the pneumotach and portable pressure transducer with one another. These embodiments of pneumotach 20″ and portable pressure transducer 50″, which are depicted in FIG. 6, require more precise, or finer, alignment between corresponding features than do the ~~previously-described~~previously described embodiments.

Please replace the paragraph [53], with the following rewritten paragraph.

[0053] Optionally, an airway adapter and complementary transducer that incorporate teachings of the present invention may be configured for multiple diagnostic functions. By way of example only, in addition to functioning as a pneumotach, an airway adapter of the present invention may also include a material sensing element, such as one or both of an infrared sensor, as described in the U.S. Patents 4,859,858 and 4,859,859, both of which issued to Knodle et al. on August 22, 1989 (hereinafter respectively "the '858 Patent" and "the '859 Patent"), and U.S. Patent 5,153,436, issued to Apperson et al. on October 6, 1992 (hereinafter "the '436 Patent"), the disclosures of each of which are hereby incorporated by this reference in their entireties, and a luminescence quenching type sensor, as described in U.S. Patent 6,325,978, issued to Labuda et al. on December 4, 2001 (hereinafter "the '978 Patent), the disclosure of which is hereby incorporated herein by this reference in its entirety. A complementary transducer would, of course, act as a pressure transducer and one or both of an infrared sensing type transducer and luminescence excitation and detection transducer.

Please replace the paragraph [56], with the following rewritten paragraph.

[0056] Luminescence-quenching portion 130 of airway adapter 120′ includes a quantity of luminescable material 132, which may be carried by a support membrane 134, within a

primary conduit ~~20~~ 22 of ~~airway adapter 120'~~ of pneumotach 20. The luminescence of luminescable material 132 is quenched to a degree indicative of an amount of an analyzed gas (*e.g.*, oxygen, nitrous oxide, etc.) or vaporized material (*e.g.*, one or more anesthetic agents) in a gas mixture (*e.g.*, respiration of an individual) to which luminescable material 132 is exposed. Airway adapter 120' also includes a window 122' through which at least a portion of luminescable material 132 may be excited into a luminescent state and through which light or other electromagnetic radiation emitted from luminescable material 132 may be detected. Examples of luminescable materials 132 and support membranes 134, as well as their positioning within airway adapter 120' relative to a window 122' thereof, and examples of materials from which window 122' may be formed are more fully described in the '978 Patent.